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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,200	05/29/2001	Shujath M. Ali	DEX-0192	2228

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EXAMINER
DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
1642	8

DATE MAILED: 08/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/807,200	ALI ET AL.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this c mmunication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-11* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

I. Claims 1, 6, drawn to a method for diagnosing prostate cancer, comprising detecting a change in the level of the CSG polynucleotide of SEQ ID NO:1.

II. Claims 1, 6, drawn to a method for diagnosing prostate cancer, comprising detecting a change in the level of the CSG polypeptide of SEQ ID NO:2.

III. Claims 2, 4, 6, drawn to a method for diagnosing metastases or onset of metastasis of prostate cancer, comprising detecting an increase in the level of the CSG polynucleotide of SEQ ID NO:1.

IV. Claims 2, 4, 6, drawn to a method for diagnosing metastases or onset of metastasis of prostate cancer, comprising detecting an increase in the level of the CSG polypeptide of SEQ ID NO:2.

V. Claims 3, 5, 6, drawn to a method for staging or change in stage of prostate cancer, comprising detecting the level of the CSG polynucleotide of SEQ ID NO:1.

VI. Claims 3, 5, 6, drawn to a method for staging or change in stage of prostate cancer, comprising detecting the level of the CSG polypeptide of SEQ ID NO:2.

VII. Claim 7, drawn to an antibody which specifically binds to the CSG polypeptide of SEQ ID NO:2.

VIII. Claims 8, 9, drawn to a method of imaging prostate cancer in a patient, using an antibody which specifically binds to the CSG polypeptide of SEQ ID NO:2.

IX. Claims 10, 11, drawn to a method for treating prostate cancer, comprising administering an antibody which specifically binds to the CSG polypeptide of SEQ ID NO:2, or administering an antibody which specifically binds to the CSG polypeptide of SEQ ID NO:2, and which is conjugated to a cytotoxic agent.

In addition, upon the election of any of groups I-VI, further election of the following patentably distinct species of the claimed invention is required:

Cells, tissues or bodily fluids.

Upon the election of any of groups III-IV, further election of the following patentably distinct species of the claimed invention is required:

Metastasis or onset of metastasis.

Upon the election of any of groups V-VI, further election of the following patentably distinct species of the claimed invention is required:

Staging or change in stage of prostate cancer.

Upon the election of group VIII, further election of the following patentably distinct species of the claimed invention is required:

Paramagnetic ion or radioisotope.

The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. When claims to different categories are present in the application, the claims will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) A product and a process specially adapted for the manufacture of said product; or (2) A product and a process of use of said product; or (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or (4) A process and an apparatus or means specifically designed for carrying out the said process; or (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(b) and (d). Group I will be the main invention. After that, all other products and methods will be broken out as separate groups (see 37 CFR 1.475(d).)

Group I, claims 1, 6, drawn to a method for diagnosing prostate cancer, comprising detecting a change in the level of the CSG polynucleotide of SEQ ID NO:1, form a single general inventive concept.

Groups III, V are additional use claimed for SEQ ID NO:1, wherein diagnosing prostate cancer is different from diagnosis of metastasis of prostate cancer and staging of cancer, because they have different objectives.

Groups II, IV, VI, VIII-IX are additional methods, which do not share the same technical feature of group I, because they use reagents that are structurally distinct from SEQ ID NO:1 of group I.

Group VII is drawn to a composition, which does not share the same technical feature of group I, because the antibody of group VII is structurally distinct from the polynucleotide of SEQ ID NO:1.

The species Cells, tissues or bodily fluids are distinct because they have different characteristics and properties.

The species Metastasis or onset of metastasis are distinct, because onset of metastasis in only one stage of metastasis.

The species Staging or change in stage of prostate cancer are distinct because they have different objective.

The species Paramagnetic ion or radioisotope are distinct, because they are different compounds with different properties.

Because these inventions are distinct for the reasons given above restriction for examination purposes as indicated is proper.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Applicant is further advised that if Applicant elects a group having species requirement, a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendement of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

MINH TAM DAVIS

August 20, 2002

SUSAN UNGAR, PH.D
PRIMARY EXAMINER